

may be placed into recesses formed in the channel bottom at specific locations along the length of each channel 42 so that only the top surface of each pad is exposed to the conjugate fluid sample solution. In various embodiments, the sensor pads 45 may be placed into each channel 42 so that a gap of between about 0.05 mm to about 0.5 mm between the top surface of each sensor pad 45 and the channel roof is provided. For example, nitrocellulose pads incorporating antibody or antigen receptors or for glass fibre pads bearing MIP receptors, the length of each of the sensor pads 45 could be set at between about 2 mm and about 20 mm.

[0082] In various embodiments, fluid flow may be regulated by setting the relative dimensions of the channel vents 47 with respect to the intended flow rate and viscosity of the sample fluid. For example, the diameter of a round channel vent 47 could be set to 0.8 mm for fluids with viscosities of 1-20 cp. However, irrespective of shape the size of the opening of the channel vents 47 may range from about 0.1 mm to 5 mm.

[0083] In various embodiments, fluid flow may be regulated either by setting the dimensions of each of the fluidic channels 42 of the chip 26 at various locations and/or by application of a surface treatment and/or by placement of pads of materials that impede fluid transport when wet, e.g., cotton, wool, etc., at appropriate locations inside a channel 42.

[0084] The ease of fluid retrieval by the cartridge 11 and of fluid flow through the channels 42, with pads 43, 45 and 46 in place, of the chip 26 may be illustrated by considering a variety of fluid types: pooled oral fluid, frozen for storage and thawed for use (viscosity near 1.0 cp); Pooled oral fluid, not frozen (viscosity near 1.0 cp); Artificial saliva with 2 mg/mL of hog gastric mucin (viscosity of approx. 1.4 cp); Aqueous buffer solutions spiked with drugs of abuse and various concentrations of bovine salivary mucin to tune viscosity from 1.0 cp to 7.2 cp; Glycerol in three dilutions providing increasing levels of viscosity from 12.79 cp, 20.61 cp to 37.15 cp, respectively. For example, when approximately 1.3 ml of oral fluid newly acquired from a donor on a swab was tested with an exemplary cartridge an average sample volume of 1.0 ml was retrieved by the cartridge 11, following less than 10 sec of compression, with the swab retaining the remainder of the sample. Using the fluids listed above we found that the cartridge 11 successfully transferred sufficient fluid samples from a swab 30 into channels 42 with the fluids flowing all the way through the reagent 43, sensor 45, and absorbent 46 pads, respectively in less than 30 sec.

[0085] The reagent pads 43 and the absorbent pads 46 may be made from, for example, glass fibre or other suitable absorbent porous material. The sensor pad 45, comprise substrates that may be made from, for example, nitrocellulose membranes, or other suitable materials, that incorporate immobilised antibodies and/or antigens and/or MIP particles, or porous or non-porous substrates that bear chemically grafted MIP layers. A porous substrate could, for example, be a macroporous, mesoporous or nanoporous oxide material, such as glass fibre, silicon dioxide, silica or alumina or another porous oxide material with a surface that can be activated to allow the attachment of initiator moieties for the initiation of a grafted MIP layer onto the substrate surface. In various embodiments, the chemically bonded thin polymer layer would have minimal swelling such that, e.g., MIP grafted substrates would be mechanically stable in different solvents, during operation and prolonged storage. In various

embodiments, the thin grafted MIP layer does not interfere with transport and provides the desired chemical selectivity. In various embodiments, grafting of MIP to pad substrates in a thin layer provides a substantial reduction in the level of released template.

[0086] In certain embodiments, the use of porous pads in combination with fluidic channel may ensure good transport for viscous liquids and heterogeneous samples about and through such substrates. The fluid to be analysed must also pass over or through a pad, which may improve the speed of the analysis assay by concentrating the small amounts of materials involved onto a small area to facilitate subsequent highly sensitive detection. Pad substrates are also useful because they are amenable to further miniaturisation and generally have high mechanical and chemical stability. In various embodiments, the use of such substrates can also facilitate, e.g., processing of the pad material, and pad placement at desired locations within each channel 42 of the fluidic chip 26, using techniques that are amenable to cost-effective, high volume manufacturing, such as surface pre-treatment with reagents or other agents, for example, blocking agents, by dipping, vapour exposure, aerosol spraying or liquid droplet deposition, and pad positioning and assembly by pick-and-place methods. In various embodiments, one advantage of the use of pick-and-place methods for chip assembly is that known-good-pads, identified by pre-screening, may be selected for placement, thereby providing a way to maximise manufacturing yield. Pick-and-place methods are also compatible with rapid, automated optical inspection during manufacturing and with subsequent product miniaturisation.

[0087] To facilitate that accurate data signal measurements may be carried out at each active sensor location on the fluidic chip 26 using the reader 13, the chip 26 is equipped with a number of mechanical alignment features 48 that provide reproducible and robust registration with the internal mechanics of the detection module 13 by direct contact. Referring to FIG. 2, in the fluidic chip 26 may be integrated into the cartridge 11 by sandwiching it between planar seals 27, and the cartridge front 21 and rear 22. According to such embodiments, when the cartridge 11 is fully assembled, the chip 26 sits over the placement features 28, which precisely position the chip 26 within the extraction chamber 23. Referring to FIG. 4, the features 49 on the fluidic chip 26 may be designed to correspond to and match with the placement features 28 in order to facilitate the positioning of the chip 26 with respect to the extraction chamber 23. In turn, this positioning facilitates the mechanical alignment feature 48 on the fluidic chip 26 to protrude outside of the cartridge 11 thereby providing direct registration between the chip 26 and the reader 13.

[0088] Various aspects and embodiments of the present inventions may be illustrated by employing the convenient format of a flow-type assay whereby a fluid sample and the products of displacement, competition or sandwich affinity assays move through a fluidic chip, producing labelled zones that can be read by eye and/or by an optical transducer.

[0089] Referring to FIG. 5a, an exemplary cartridge 11 is shown standing upright with a swab 30 inserted into the extraction chamber 23 and with the hinged lid 24 in open 51 and closed 52 positions, respectively. To carry out a fluorescence-based assay using oral fluid, for example, a fluid sample of sufficient volume is collected by a swab 30. Upon insertion of the swab 30 into the extraction chamber 23 and closure of the hinged lid 24, the swab head 32 is compressed